

UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of)
SCHERING-PLOUGH CORPORATION, a corporation,)))
UPSHER-SMITH LABORATORIES, a corporation,) Docket No. 9297
and)
AMERICAN HOME PRODUCTS CORPORATION, a corporation.))))

TO: The Honorable D. Michael Chappell Administrative Law Judge

MOTION TO AMEND PROTECTIVE ORDER

"In an antitrust action where the essence of the charge is that defendants have engaged in activity in restraint of competition, it is not unusual to touch on, or even to probe, matters at the heart of the business dealings and competitive relationships of the parties." Maritime Cinema Serv. Corp. v. Movies En Route, Inc., 60 F.R.D. 587, 590 (S.D.N.Y. 1973). This proceeding is no exception. As part the Federal Trade Commission's investigation regarding potassium supplement products, it demanded from non-party KV Pharmaceutical Company many of KV's most commercially sensitive documents. As a result, although KV has never been accused of any wrongdoing in this matter, it may be substantially harmed by the dissemination of its

proprietary information to rival pharmaceutical manufacturers. KV is particularly distressed that under the terms of the Protective Order, *all* of KV's documents could be examined, without restriction, by the Director of Scientific Affairs of respondent Upsher-Smith Laboratories.

Protective Order, ¶ 5. KV seeks to amend the Protective Order to prevent this individual from such unrestricted access.

There can be no question that the documents KV produced are of the utmost sensitivity. KV has produced its core marketing information regarding potassium supplement products, including proprietary sales, pricing, and profit information, as well as projections of future sales. Ex. A. Mariani Declaration, ¶ 2. KV has disclosed its plans regarding additional commercial products, and projections regarding sales of those products. See id. KV has also revealed detailed specifications regarding how it makes its products, and its efforts at product improvements and line extensions. See id. at ¶ 2, 3. This is information that KV takes pains to protect from disclosure, both during the ordinary course of business and within the context of this proceeding. Id. at ¶ 4. When the FTC first compelled the production of documents and information, KV explicitly demanded the full protections available and marked every page "confidential." Upon receiving the Protective Order, to make sure that the documents received as much protection as possible, KV shouldered the expense of reviewing its production another time, marking its documents "Restricted Confidential" where appropriate, re-copying the documents, and producing them to each of the four parties. If all these protections are rendered ineffective, and KV's information is revealed to rival executives, KV is likely to suffer substantial commercial harm. Id. at ¶¶ 3, 6.

The Protective Order recognizes that disclosure of non-party information can cause substantial harm, and contains an elaborate mechanism for protecting "Confidential" and

"Restricted Confidential" information. And while "in-house counsel" are permitted to view all documents, the Protective Order demands that such counsel must be people "who do not have day to day business responsibilities." Protective Order, ¶ 5. However, despite this restriction, Upsher-Smith designated as its in-house counsel "Mark Robbins, Director of Scientific Affairs." Id.

A head of "Scientific Affairs," at KV and generally in the industry, is the last person who ought to be viewing the confidential information of rival manufacturers. See Mariani Dec., ¶ 6. KV's Vice President, Scientific Affairs, has input into all aspects of product development. Id. at ¶ 5. Scientific Affairs is responsible for evaluating the likelihood of success of potential development projects, and then oversees the ensuing research and development efforts. Id. A rival Scientific Affairs department may well benefit from the produced documents that explain exactly how KV makes its products, and the hurdles KV has faced during the development process. Scientific Affairs also helps develop the methods for analytic and clinical testing of the products, and again could gain an unfair advantage from dissemination of KV's specifications and results for such tests. See id. Finally, Scientific Affairs is responsible for obtaining regulatory approvals from the Food and Drug Administration, a process that may be made easier by analyzing KV's experience before that agency, as reflected in the documents it has produced. See id.

In <u>Sullivan Marketing</u>, Inc. v. Valassis Comm., Inc., 1994 WL 177795, *3 (S.D.N.Y. 1994), the Court found that an "in-house" counsel should not be permitted to see confidential documents where, (as here), "he not only provides legal advice, but he also manages specific departments." Other courts came to a similar conclusion. <u>Ball Mem. Hosp., Inc. v. Mutual</u> Hosp. Ins., Inc., 784 F.2d 1325, 1345-46 (7th Cir. 1986) (affirming protective order restricting

disclosure of certain information to outside counsel who agree not to represent any hospital for a period of 18 months); see Scovill Mfg. Co. v. Sunbeam Corp., 61 F.R.D. 598, 602 (D. Del. 1973) (information to be disclosed "to trial counsel only to prevent its improper use by [defendant]"). As the Sullivan Court explained:

where advice on a seemingly legal issue . . . is sought, counsel's intimate knowledge of a competitor's pricing policies could surely influence the nature of the advice given. 'It is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so.' <u>F.T.C. v. Exxon Corp.</u>, 636 F.2d 1336, 1350 (D.C. Cir. 1980).

Sullivan, 1994 WL 177795 at *3 (internal citations original). KV is a non-party, involved in this proceeding only because its information was obtained by compulsory process. "[A]s [a] third part[y], [KV's] requests . . . deserve special solicitude. As a policy matter, extensions of confidential or in camera treatment in appropriate cases involving third party bystanders encourages cooperation with future adjudicative discovery requests." In the Matter of Kaiser Aluminum & Chem. Corp., 103 F.T.C. 500 (1984).

KV's commercial interests should be protected, and the Protective Order modified so that Mr. Robbins may not be designated as eligible to examine KV's most sensitive information.

DATED: May 29, 2001

Respectfully submitted,

Jonathan Berman

(D.C. Bar No. 445169)

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Attorney for Non-Party KV Pharmaceutical Company

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DECLARATION OF DR. ELIO MARIANI

Dr. Elio Mariani, pursuant to 28 U.S.C. § 1746, declares as follows:

- 1) I hold the position of Vice President, Scientific Affairs at KV Pharmaceutical Company. I have held this position since July, 1996. I make this declaration in support of KV's Motion to Amend Protective Order.
- 2) In earlier proceedings in this matter, I and others at KV searched our files in order to produce documents and information to the Federal Trade Commission. I understand that the information produced includes: non-public sales, profit, and pricing information and sales projections; planning documents for new products and line extensions; product specifications; protocols for stability, clinical tests, and analytical methods; research and development plans; research and development reports; results from a variety of product tests; batch records; and non-public regulatory applications and other filings.
- 3) The information provided to the FTC is of critical strategic importance to KV. The documents listed above reveal key marketing date, including projections of how much we anticipate selling in the future. The documents describe how we make our products, and how we are trying to make them better. The documents also indicate what products we will sell in the

future, how we intend to make those products, the research issues we have encountered, and issues that need to be overcome before the eventual product launch. Dissemination of this information to actual or potential competitors is likely to result in substantial commercial harm.

- 4) KV is rigorous in preserving the confidential and proprietary nature of the information and documents described above. Internal procedures exist to ensure that such information is not made public, and KV's employees are trained to understand and observe these confidentiality policies. I understand that regarding the specific documents provided to the FTC, KV's counsel was instructed to (and did) attempt to preserve the confidentiality of these documents as much as possible by asserting all applicable statutory and regulatory protections.
- 5) As Vice President, Scientific Affairs, I am responsible for directing KV's research and development efforts. I participate in the selection of new commercial products by assessing KV's ability to develop those products. I am also responsible for overseeing the development process, and for periodically re-assessing the probability of successful development. I participate in the clinical testing of products, both through internal efforts and through contracting with and monitoring outside research firms. I also supervise KV's efforts to obtain and maintain regulatory approval for KV's products.
- 6) I believe that at most or all drug manufacturers there is a person with job duties similar to mine. I also expect that employees of drug manufacturers with a title indicating responsibility for "Scientific Affairs" generally have job responsibilities similar to my own. KV would likely suffer substantial commercial harm if an employee of a competitor or possible competitor, with job responsibilities similar to my own, were to be given free access to the information that KV provided to the FTC. Such a person may be in a position both to predict the extent and success of KV's product line, and/or to use KV's information to further competing research and development efforts, or to avoid potential regulatory hurdles.
- 7) I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dr. Elio Mariani

Executed this 25 Hday of May, 2001

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OH	RDER
Upon the motion of KV Pharmaceutical	Company, and for good cause shown, IT IS
HEREBY ORDERED that the Protective Ord	er entered in this case and dated May 10, 2001, is
modified so that the following words are delete	ed from paragraph 5:
"For Respondent Upsher-Smith, Robbins, Director of Scientific A	, the designated individual is Mark, Affairs"
Consequently, Mr. Robbins shall not be consid	ered "in-house counsel" within the meaning of the
portions of the protective order relating to the c	lisclosure of Confidential Discovery Material.
ORDERED:	D. Michael Chappell Administrative Law Judge
Date:	

CERTIFICATE OF SERVICE

I hereby certify that today I caused a copy of the attached document, entitled Motion to Amend Protective Order to be delivered by facsimile and U.S. Mail to:

Cathy Hoffman, Esq. Arnold & Porter 555 12th St., N.W. Washington, DC 20004-1206

Laura Shores, Esq. Howrey Simon Arnold & White 1299 Pennsylvania Ave., N.W. Washington, DC 10004-2402

Christopher M. Curran, Esq. White & Case 601 13th St., N.W. Washington, DC 20005

Karen Bokat, Esq. FTC 601 Pennsylvania Ave., N.W. Rm. 3112 Washington, DC 20580 By-Hand Delivery to:

The Honorable D. Michael Chappell Federal Trade Commission 600 Pennsylvania Ave., N.W. Washington, D.C. 20580

Jorathur Bernan Jonathan Berman

Jones, Day, Reavis & Pogue

DATED:

May 29, 2001